UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/572,316 | 03/17/2006 | Robert Jongejan | 27233U | 8025 |

34375 7590 04/23/2010

NATH & ASSOCIATES PLLC
112 South West Street
Alexandria, VA 22314

| EXAMINER | |
|---|---|
| BLIZZARD, CHRISTOPHER JAMES | |
| ART UNIT | PAPER NUMBER |
| 3771 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 04/23/2010 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/572,316 | JONGEJAN ET AL. | |
| | Examiner | Art Unit | |
| | CHRISTOPHER BLIZZARD | 3771 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-9,11-22 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-22 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5, 7, 8, 12-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf (5,809,997) in view of Olbrich (6,733,464).

4. Regarding claim 1, Wolf discloses a compliance monitor for a drug delivery device for administering a drug, comprising; a switch, in the form of a strain gauge dynamic sensing arm (1555), actuatable by a user on delivering a dose from the device (Abstract); a sensor (1560) for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose (column 19, lines 21-41); and a processor (1540) coupled to the switch (1555) and the sensor (1560) (fig. 16) for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is a temperature sensor (425), in the form of a thermistor, for sensing body temperature (columns 15,16; lines 58-67, 1-5), but does not discloses the sensor mounted so that the temperature sensor enters or contacts the user's mouth when a mouthpiece is placed in the mouth. Olbrich discloses a sensing device for use with a drug delivery device (column 15, lines 54-57) that includes a temperature sensor that enters or contacts the user's mouth when the mouthpiece is placed in the mouth (column 8, lines 64-67; column 9, lines 1-3). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the compliance monitor of Wolf with the mounting of a temperature sensor as taught by Olbrich in order to provide the advantage of a fast response to user contact of device.

5. Regarding claim 2, Wolf in combination with Olbrich teach the claimed device, wherein Wolf discloses a compliance monitor which does not affect the normal operation of the drug delivery device (column 3, lines 24-27).

6. Regarding claim 3, Wolf in combination with Olbrich teach the claimed device, wherein Wolf discloses a compliance monitor (1200)) which is removably attachable to the drug delivery device(1210) (column 17, lines 7-16).

7. Regarding claim 4, Wolf in combination with Olbrich teach the claimed device, wherein Wolf discloses a compliance monitor comprising a clock coupled to a processor (605) and in which the time of actuation of the switch is recorded (column 6, lines 25-30).

8. Regarding claim 5, Wolf in combination with Olbrich teach the claimed device, wherein Wolf discloses a compliance monitor wherein proper positioning of the drug delivery device is positioning in contact with or relative to the user's mouth, nose or skin (column 15, lines 58-60).

9. Regarding claim 7, Wolf in combination with Olbrich teach the claimed device, wherein Wolf discloses a compliance monitor wherein the drug delivery device is for oral administration of the drug (column 15, lines 58-60).

10. Regarding claim 8, Wolf in combination with Olbrich teach the claimed device, wherein Wolf discloses a compliance monitor wherein the drug delivery device is an inhaler operated by the user depressing a pressurized canister (1590) containing the drug, and wherein the switch is a pressure-operated switch (1555) actuatable as the user depresses the canister (figs. 17b and 17c).

11. Regarding claim 12, Wolf in combination with Olbrich teach the claimed device, wherein Olbrich teaches the device further comprising a conductivity sensor for sensing body conductivity (column 9, lines 18-31)

12. Regarding claim 13, Wolf in combination with Olbrich teach the claimed device, wherein Wolf discloses a compliance monitor in which a change in an output of the sensor characteristic of correct use of the drug delivery device is used to determine whether the device was properly positioned when the dose was delivered (column 15, lines 55-65).

13. Regarding claim 14, Wolf in combination with Olbrich teach the claimed device, wherein Wolf discloses a compliance comprising an output (415) for downloading data to a docking station or a computer (fig. 10).

14. Regarding claim 15, Wolf in combination with Olbrich teach the claimed device, wherein Wolf discloses a compliance monitor in which the data comprises a compliance record of use of the drug delivery device, including a record of whether the sensor output indicates that the device was properly positioned on each occasion that a dose has been delivered (column 3, lines 58-69) (column 15, 58-60).

15. Regarding claim 16, Wolf in combination with Olbrich teach the claimed device, wherein Wolf discloses a docking station (2030) for use with a compliance monitor (fig. 20).

16. Regarding claim 17, Wolf in combination with Olbrich teach the claimed device, wherein Wolf disclose a compliance monitor with computer-readable medium carrying a computer program for programming a general purpose computer to receive and process data downloaded from a compliance monitor (column 6, lines41-50).

17. Regarding claim 18, Wolf in combination with Olbrich teach the claimed device, wherein Wolf discloses a compliance monitor with a drug delivery device (Abstract).

18. Regarding claim 19, Wolf in combination with Olbrich teach the claimed method, wherein Wolf discloses a method of using a compliance monitor to monitor use of a drug delivery device for administration of a drug, comprising the steps of: determining when a user operates the device to deliver a dose of the drug (column 1, lines 11-20); sensing whether the device is properly positioned in contact with or relative to the user's body when the dose is delivered (column 15, lines 55-60); and recording for each operation of the-device whether or not the device was properly positioned (column 16, lines 2-5).

19. Regarding claim 20, Wolf in combination with Olbrich teach the claimed method, wherein Wolf discloses a method comprising the step of determining and recording the time of each operation of the device (column 1, lines 16-17).

20. Regarding claim 21, Wolf in combination with Olbrich teach the claimed method, wherein Wolf discloses a method in which the drug delivery device is for oral administration of the drug and proper positioning of the device is proper positioning in the user's mouth (column 15, lines 58-60).

21. Regarding claim 22, Wolf in combination with Olbrich teach the claimed method, wherein Wolf discloses a method comprising a step of downloading recorded data from the compliance monitor to a docking station or a computer to allow a compliance record to be reviewed (fig. 20) (column 6, lines 41-45).

22. Regarding claim 25, Wolf in combination with Olbrich teach the claimed method, wherein Wolf discloses a compliance monitor wherein the drug delivery device is for oral administration by inhalation (column 15, 55-60).

23. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf (5,809,997) in view Olbrich (6,733,464) as applied to claim 1 above, and further in view of Reinhold (7,073,499 B1).

24. Regarding claim 6, Wolf in combination with Olbrich teach the claimed device except for wherein the drug delivery device is for topical administration of the drug. Riinhold discloses a drug delivery device, in the form of an inhaler, for topical administration of a drug (column 14, lines 61-63). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the combination of Wolf and Olbrich with a drug delivery device as taught by Reinhold in order to provide the advantage of allowing the invention to be used by patients with a wider range of medication needs.

25. Regarding claim 9, Wolf and Olbrich in combination with Reinhold teach the claimed device wherein Reinhold teaches the use of drug delivery devices including dry powder inhalers, pressurized metered dose inhalers and nebulisers (column 1, lines 25-28).

26. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf (5,809,997) in view Olbrich (6,733,464) as applied to claim 1 above, and further in view of in view of Trueba (6,684,880).

27. Regarding claim 11, Wolf in combination with Olbrich discloses the claimed invention except further comprising a light sensor for sensing when the sensor is covered. Truedba teaches a compliance monitor with a light sensor for sensing when the sensor is covered (column 13, lines 28-31). It would have been obvious to one of

ordinary skill in the art at the time of the invention to provide the combination of Wolf and Olbrich with a light sensor as taught by Trueba in order to provide the advantage of providing a simple way of determining if the invention was properly used (column 13, lines 28-31).

### *Response to Arguments*

28. Applicant's arguments filed 1/29/10 have been fully considered but they are not persuasive. Applicant's argument that the sensor of Wolf is not measuring body temperature is not persuasive because the airflow temperature that it senses is from within the body and is therefore a body temperature. Applicant's argument that the sensor of Wolf does not detect whether the device is properly positioned is not persuasive because the sensor of Wolf detects proper inhalation sequence which inherently could only be considered proper if the device was properly positioned. Applicant's argument concerning Wolf and Olbrich not being combinable is not persuasive because changing the type or location of a sensor to another known type or known location is a mere design consideration and would have been obvious to one of ordinary skill in the art.

### *Conclusion*

29. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/
Examiner, Art Unit 3771

/Steven O. Douglas/
Primary Examiner, Art Unit 3771